

REMARKS

Appreciation is hereby expressed to Examiner Howard for the interview so courteously granted on November 3, 2005. The Examiner is also thanked for the very detailed final Office Action and the suggestions for obviating the prior art references.

Pursuant to that interview, Claim 17, the only independent claim in the case, is hereby amended to more definitely set forth the invention and obviate the rejection. In particular, in Claim 17, the term "comprising" has been replaced by the expression "consisting essentially of". In addition, Claim 17 has been amended to set forth the average molecular weight of the water swelling polymer. Support for the amendment of Claim 17 can be found in the Specification on page 13, lines 1-4. The importance of these changes is discussed hereinafter. The present amendment is deemed not to introduce new matter. Claims 17-25 remain in the application, claims 1-16 having been previously cancelled in a preliminary amendment.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(e) as being anticipated by either of Sun, et al. (US Patent 6,678,554), or Iga, et al. (US Patent 6,322,550).

At the outset, it is noted that Claim 17 has been amended to substitute the term "consisting essentially of" for the original term "comprising". In the final rejection on page 6, the Examiner pointed out that the expression "comprising" allows antibacterial layers and Suzuki teaches Eudragit E and that the same polymer would be expected to give the same property. In order to obviate the rejections, applicants have restricted the scope of Claim 17 so that it would not allow any additional layers such as taught by Suzuki or other prior art of record. The Examiner is thanked for the suggestion for obviating the rejections.

In addition, during the interview the undersigned mentioned that in Sun, et al., the polymer Eudragit S or Eudragit E may be used to prevent an increase in the pH of the electrode medium in the fluid reservoir 100 rather than maintaining the pH of the electrode medium. It was also mentioned that Sun, et al. discloses an active agent reservoir 120 containing an active agent in solution during electrotransport delivery, which is separated by semi-permeable membrane 108 from the fluid reservoir 110. It was pointed out in the interview that this is illustrated in Fig. 1 and described in column 8, lines 24-27.

Moreover, the semi-permeable membrane 108 in Sun, et al. inhibits the active agent from contacting the surface of electrode 112 as disclosed in column 8, lines 43-44. On the basis of this disclosure, it is respectfully submitted that one of ordinary skill in the art, with the Sun, et al. reference being considered as a whole, would reasonably conclude that this reference does not disclose using an agent for controlling pH variations in the active agent reservoir 120.

In the present invention, there is no semi-permeable membrane installed between an active agent reservoir and a fluid reservoir as in Sun, et al. Instead, the structure for iontophoresis consists essentially of an electrically conductive layer containing at least one partially ionized active ingredient and a water swelling polymer having an average molecular weight of 100,000 – 1,000,000 dalton and having a polarity selected considering the dissociation of the active ingredient for controlling pH variation.

According to the present invention, the electrically conductive layer 102 can be directly attached to the skin as shown in Fig. 1 by using the water swelling polymer having pH dependence solubility and an electrically conductive layer using iontophoresis, without decreasing the drug delivery rate, and thus enabling safe drug delivery to a living body (Specification, page 7, lines 10-

14). It is therefore respectfully submitted that these effects of the present invention cannot be derived from the device disclosed by Sun, et al. since the pH variation control in Sun, et al. is not carried out in the active agent reservoir 120, but only in the fluid reservoir 110 as discussed above. In view of the present amendment to the claims and the discussion set forth above, it is respectfully submitted that Sun, et al. fail to anticipate or render unpatentably obvious the subject matter now called for in the claims herein. For these reasons, it is respectfully submitted that the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In the final rejection the Examiner again predicates the rejection on Iga, et al. on the Doctrine of Inherency asserting that the pH adjusting function claimed by applicant is inherent in the gel disclosed by Iga, et al.

However, it is respectfully submitted that there is no disclosure in Iga, et al. of the use of a partially ionized active ingredient and a water swelling polymer having an average molecular weight of 100,000 – 1,000,000 dalton and having a polarity selected considering the dissociation of the active ingredient for controlling pH variation. For this reason, it is respectfully submitted that Iga, et al. in no way anticipates under 35 U.S.C. § 102(e) the subject matter now called for in the claims herein.

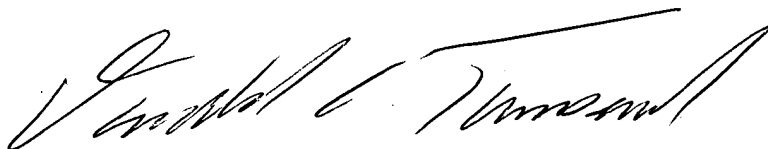
With the amendment of Claim 17 to distinguish from Iga, et al., it is respectfully submitted that the Examiner would be justified in no longer maintaining the final rejection. Withdrawal of the final rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance and early action and allowance thereof is accordingly respectfully requested.

In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA

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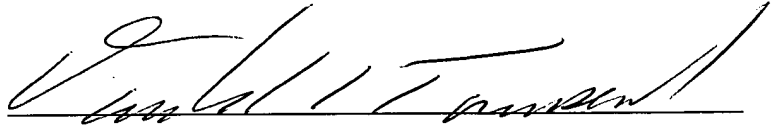
CERTIFICATE OF MAILING

I hereby certify that this Amendment After Final Rejection and Transmittal, in
Docket No. MUR-022-USA-D, Serial No. 10/674,419, filed October 1, 2003, was deposited
with the United States Postal Service with sufficient postage as first class mail in an envelope
addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On November 14, 2005

Donald E. Townsend

A handwritten signature in black ink, appearing to read "Donald E. Townsend", is written over a horizontal line.